REMARKS

Applicants have amended claims 1-14, and 17.
Applicants have introduced new claims 22-35.

Support for the amendments to claims 1 and 13 is to be found in the specification at paragraphs 0002, 0021, and 0056-0058 (creating a fistula); paragraphs 0006, 0024, 0034, 0061, Figures 1 and 3, and the abstract (systemic artery and systemic vein); paragraph 0023 (blood flow bypasses the peripheral circulation); paragraph 0027 to 0033 and figure 10A (cardiac output).

Support for the amendments to claims 2 and 14 is to be found in the specification at paragraph 0061 (iliac artery and vein, femoral artery and vein, axillary artery and vein, and subclavian artery and vein)

Support for the amendment to claim 3 is to be found in the specification at paragraphs 0005, 0010, 0036-0040 and in the abstract (respiratory or cadio-respiratory condition); at paragraph 0005, 0010, and the abstract (cardiac condition); and at paragraph 0005, 0010, and the abstract (circulatory condition).

Support for the amendment to claim 4 is to be found in the specification at paragraphs 0007, 0010, Figure 1, in the abstract, and in originally filed claims 1, 8, and 13 (decreases systemic vascular resistance).

Support for the amendment to claim 5 is to be found in the specification at paragraphs 0006, 0023, 0024, 0045, 0046, 0059, Figures 1, 2, and 3, and the abstract (implanting shunt between systemic artery and systemic vein).

Support for the amendment to claim 6 is to be found in the specification at paragraphs 0007, 0043, and originally filed claim 15 (cross sectional area of about 19 mm^2 to about 750 mm^2).

Support for the amendment to claim 7 is to be found in the specification at paragraphs 0007, 0043, and in originally filed claim 16 (length of about 2.5 mm to about 15 mm).

Support for the amendment to claim 8 is to be found in the specification at paragraphs 0007, 0043, and in originally filed claim 17 (radius of about 2.5 mm to about 15 mm).

Support for the amendment to claim 9 is to be found in the specification at paragraphs 0007, 0044, an in originally filed claim 22 (coating to prevent clot formation or atheroma formation).

Support for the amendment to claim 10 is to be found in the specification at paragraphs 0008, 0010, 0025, 0026, 0048-0054, figures 5, 6, and 7, in the abstract, and in originally filed claims 9, 10, 18 (controlling the flow rate through the shunt).

Support for the amendment to claim 12 is to be found in the specification at paragraph 0056-0058 and in originally filed claim 12 (creating fistula using a surgical procedure).

Support for the amendment to claim 17 is to be found in the specification at paragraph 0007, 0042, 0043, 0053, and Figures 4 and 7 (cross sectional area of the shunt device having a radius).

Support for new claims 23-26, 34 and 35 is to be found in the specification at paragraph 024 (proximal or distal of the renal arteries).

Support for new claim 27 is to be found in the specification at paragraphs, paragraphs 0002, 0006, 0021, 0023, 0024, 0026, 0034, 0056-0058, 0061, Figures 1, 3, and 10A, in the abstract, and in the claims as originally filed.

Support for new claim 28 is to be found in the specification at paragraph 0049.

Support for new claim 29 is to be found in the specification at paragraph 0043.

Support for new claim 30 is to be found in the specification at paragraph 0049

Support for new claim 31 is to be found in the specification at paragraphs 0031, 0032, 0043 and 0049.

Support for new claim 32 is to be found in the specification at paragraph 0056 and in Figure 10.

Support for new claim 33 is to be found in the specification at paragraph 0022.

Applicants have amended claims 1, 4, 5, 7-11, and 17 to recite proper antecedent basis.

No new matter has been added by these amendments. Applicants respectfully request entry of the present amendment.

Claim Rejections under 35 USC § 101

1) The Examiner has rejected claims 4, 6, and 8 under 35 USC § 101, because the claimed invention is not supported by either a specific and substantiated utility or a well-established utility.

The Examiner stated that applicant attempted to claim that the recited method increases O_2 concentration in the patient's blood, increases cardiac output, and decreases a particular vessel's blood pressure. The Examiner further stated that applicant failed to set forth any evidence that such an increase is provided by the method and added that the specification merely provided that such shunting *may* increase a patient's O_2 concentration, cardiac output, or decrease a particular vessel's blood pressure.

2) Applicants have amended claim 4 to recite: "The method as set forth in claim 1, wherein said method decreases systemic vascular resistance".

Applicants have amended claim 6 to recite: "The method as set forth in claim 5, wherein said shunt has a cross sectional area of about 19 mm^2 to about 750 mm^2".

Applicants have amended claim 8 to recite: "The method as set forth in claim 5, wherein said shunt has a radius of about 2.5 mm to about 15 mm".

Applicants respectfully draw the Examiner's attention to the Examples section of the specification at page 19, paragraph 0056, at page 20, paragraphs 0057-0058, and also to the drawings disclosed in Figures 10, 11, and 12. Applicants therein clearly show experimental data that illustrates that the method of implanting an aorto-caval fistula in rats was associated with increased aortic blood flow (AF), with increased partial pressure of oxygen in arterial blood (PaO_2) in rats (Figure 10), and attenuates the development of pulmonary arterial hypertension (Figure 11). Applicants further submit that it is well known in the art that an increased partial pressure of oxygen in arterial blood (PaO_2) is associated with increased hemoglobin O_2 saturation in arterial blood.

Applicants submit that the specification provides a specific and substantial or a well-established utility by disclosing that the method increases aortic blood-flow (Figure 10A), the partial pressure of O_2 dissolved in the arterial blood plasma (Figure 10B of the application), increases the hemoglobin O_2 saturation in arterial or venous blood (inherent to Figure 10B of the application), increases the O_2 concentrations in arterial or venous blood (Figure 10B of the application), or decreases the mean pulmonary artery pressure in arterial blood (Figure 11 of the application).

Applicants therefore respectfully submit that, contrary to the Examiner's submission, the method does increase O_2 concentration, cardiac output, or decrease a particular vessel's blood pressure.

Applicant, upon a request from the Examiner, will be happy to submit further data derived from human studies and pig studies showing that using the claimed apparatus and the claimed methods result in the same physiological effects.

Therefore, Applicants have presented a "specific utility", a "substantial utility", and a "well-established utility" and that satisfies 35 U.S.C. § 101. Applicants respectfully request that the Examiner withdraw the rejection of claims 4, 6, and 8 under 35 USC § 101.

Claim Rejections under 35 USC § 112, first paragraph

3) The Examiner has rejected claims 4, 6, and 8 under 35 USC § 112, first paragraph,

The Examiner stated that since the claimed invention (claims 4,6, and 8) was not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth at page 2 of the instant Office action (mailed 27 September 2006), one skilled in the art clearly would not know how to use the claimed invention.

4) To the extent the Examiner's rejection of the patented invention under 35 U.S.C. § 112 is based on the Examiner's rejection of claims for lack of utility under 35 U.S.C. § 101, it must be overturned.

The rejection under 35 U.S.C. § 112, first paragraph, set forth in the Office Action (mailed 27 September 2006) is based on the assertions discussed above, i.e., that the claimed invention lacks patentable utility. To the extent that the rejection under § 112, first paragraph, is based on the allegation of lack of patentable utility under § 101, it fails for the same reasons, as described in Applicants' response to the rejections of claims 4, 6, and 8 under 35 U.S.C. § 101 above and therefore Applicants submit that those skilled in the art would know how to use the claimed invention.

Therefore, Applicants respectfully submit that claims 4, 6, and 8 satisfy the written description and utility requirements of 35 U.S.C.§ 112, first paragraph and respectfully request that the rejection of claims 4, 6, and 8 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Objections

5) The Examiner has objected to claims 1-11 as being incomplete for omitting essential steps, such omission amounting to a gap between the steps (MPEP § 2172.01)

The Examiner stated that, in claim 1, Applicants attempted to claim a therapeutic method by decreasing the systemic vascular resistance of a patient by providing a shunt, but never actually claimed the step of implanting the shunt within the patient. The Examiner deemed that for the purposes of examination on the merits and in the interest of compact prosecution that the method claimed by Applicants includes the step of implanting the claimed shunt.

The Examiner then stated that, in claims 3, 5, and 7, Applicants attempt to further define a method, but failed to set forth any additional steps in the method. The Examiner deemed that for the purposes of examination that the claimed method may be used to treat a respiratory, cardiac, or circulatory condition.

The Examiner therefore required appropriate correction.

6) Applicants thank the Examiner for assuming that the method claimed by Applicants includes the step of implanting the claimed shunt.

Applicants have amended claim 1 to recite: "A therapeutic method for increasing cardiac output in a subject, the method comprising: creating a fistula between a systemic artery and a systemic vein of said subject, said fistula adapted to allow blood flow rate therethrough of at least 5 ml/min, wherein said blood flow through the fistula bypasses the peripheral microcirculation, and wherein creation of said fistula results in an increase in the cardiac output in said subject".

Applicants have amended claim 3 to recite: "The method as set forth in claim 1, wherein said method is used to treat a condition selected from the group consisting of a respiratory condition, a circulatory condition, and a cardiac condition".

Applicants have amended claim 5 to recite: "The method as set forth in claim 1, wherein the creation of the fistula is provided by implanting a shunt between a systemic artery and a systemic vein of said subject".

Applicants have amended claim 7 to recite: "The method as set forth in claim 5, wherein said shunt has a length of about 2.5 mm to about 15 mm".

7) The Examiner has objected to claim 17 because it recites the limitation "the radius" in line 1 but that there is insufficient antecedent basis for this limitation in the claim. The Examiner therefore required appropriate correction. The Examiner deemed that for the purposes of examination that the Examiner has interpreted "the radius" to comprise the internal radius of the claimed shunt device.

8) Applicants have amended claim 17 to recite: "The apparatus as set forth in claim 13, wherein the cross sectional area of the shunt device has a radius in the range of about 2.5 mm to about 15 mm".

Therefore, with the amendments to claims 1, 3, 5, 7, and 17, Applicants respectfully request that the objections to claims 1-11 and 17 be withdrawn.

Double Patenting

9) The Examiner stated claims 1-22 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/961,731.

The Examiner stated that a timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or § 1.321(d) may be used to overcome an actual or provisional rejection.

10) Applicants respectfully submit that copending Application No. 10/961,731 is a continuation-in-part of the instant application having a filing date subsequent to that of

the instant application. Applicants state that a terminal disclaimer may be filed during prosecution of copending Application No. 10/961,731 at an appropriate time.

Applicants submit that a terminal disclaimer will be filed in the instant Application if the claims of copending Application No. 10/961,731 are found allowable prior to the instant pending claims.

Applicants therefore respectfully request that the Examiner withdraw the provisional obviousness-type double patenting rejection of claims 1-22.

Claim Rejections under 35 USC § 103(a)

11) The Examiner has rejected claims 1, 3-11, 13-15, and 18-21 under 35 USC § 103(a) as being unpatentable over US 5,662,711 to Douglas.

The Examiner stated that in the specification and figure, Douglas discloses the method substantially as claimed by Applicants. The Examiner then stated that with regard to claims 1, 9, and 18, as interpreted by the Examiner, Douglas discloses a method of reducing a patient's vascular resistance by using a resistor 110 to control fluidic flow through a shunt 100 implanted between the pulmonary artery and another systemic blood vessel which may be a vein (sic) (see Douglas Figure 2 and column 1, lines 65-67 and column 2, lines 1-20).

With regard to claim 1, drawn to the flow rate of fluid through the shunt, the Examiner stated that it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the rate of flow through the Douglass shunt to the rate claimed by Applicant.

With regard to claims 13 and 15, drawn to the cross-sectional area of the shunt, the Examiner stated that Douglas specifically teaches that the rate of flow through the shunt is a result-effective variable that may be used to achieve the desired oxygen saturation level (see Douglas column 2, lines 29-38). The Examiner stated that it would have been

obvious to one having ordinary skill in the art at the time the invention was made to adjust the rate of flow through the Douglas shunt to the rate claimed by Applicants.

With regard to claims 3, 5, and 7, the Examiner stated that Douglas discloses that the method may be use to convey blood from the aorta to the pulmonary system to oxygenate the blood, thereby providing a respiratory therapy, congenital heart defects and thereby cardiac therapy, and reduce vascular resistance and thereby circulatory therapy (see Douglas column 1, lines 4-6).

With regard to claims 4, 6, and 8, the Examiner stated that Applicants failed to disclose that their method was actually capable of providing the claimed benefits. The Examiner further stated that since the shunt and methods disclosed by Applicants satisfies the limitations of Applicants' claims, the Douglas shunt and methods are capable of producing the results claimed by Applicants, thereby meeting the limitations of the claims.

With regard to claims 10 and 19, the Examiner stated that Douglas discloses that the restrictor 110 in shunt 100 may be selectively activated by controller 120 to control fluid flow rate through the shunt based on signals from sensor 114 that monitors oxygen saturation (see Douglas column 2, lines 11-28 and column 4, lines 19-25). The Examiner then stated that Douglas discloses that the device is capable of operating as claimed by the Applicants, meeting the limitations of the claims.

With regard to claim 11, the Examiner stated that Douglas discloses that the controller 120 is capable of controlling the restriction of the shunt 100 via bladder 130, which adjusts the cross-sectional area of the shunt (see Douglas column 4, lines 19-59). The Examiner then stated that Douglas discloses that the device is capable of operating as claimed by the Applicants, meeting the limitations of the claims.

With regard to claim 14 and its recitation of the site of implantation of the claimed device, the Examiner stated that Douglas discloses that the shunt may be implanted

between an aorta and another systemic blood vessel (see Douglas column 2, lines 11-15) indicating that the device may be implanted in Applicants' claimed location, meeting the limitations of the claim.

With regard to claim 20, the Examiner stated that Douglas discloses that the shunt device 100 comprises a restrictor 110 connected to controller 120 that uses bladder 130 as a flow control element to control flow though the shunt (see Douglas column 2, lines 11-38).

With regard to claim 21,drawn to the automatic, self-adjusting operation of the shunt, the Examiner stated that Douglas discloses that the controller 120 is capable of controlling the restriction of the shunt 100 via bladder 130, which adjusts the cross-sectional area of the shunt (see Douglas column 4, lines 19-59). Furthermore, the Examiner stated, Douglass discloses that the shunt and restrictor may be manually controlled or controlled based on signals other than those from oximeter 114 (see Douglas column 5, lines 35-50) and therefore that Douglas discloses that the device is capable of operating as claimed by the Applicants (i.e. automatically), meeting the limitations of the claims

> "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *Graham v. John Deere Co.*, 148 USPQ 459, 467 (S.Ct. 1966).
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> "To establish obviousness under section 103, "[b]oth the suggestion and the expectation of success must be founded on the prior art and not in applicant's disclosure." In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ 1529, 1531 (Fed. Cir. 1988).
>
> "The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. . . . It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596, 1598 (CAFC 1988).

> "Unless the [prior art] disclosures would have suggested to one of ordinary skill in the art at the time the invention was made that a [combination] should be so employed, [a] claim . . . is not unpatentable under 35 U.S.C. § 103." *In re Bond*, 15 USPQ2d 1566, 1569 (CAFC 1990).
>
> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." *In re Geiger*, 2 USPQ2d 1276, 1278 (CAFC 1987). See also *Carella v. Starlight Archery*, 231 USPQ 644, 647 (CAFC 1986) and *ACS Hosp. Sys. v. Montefiore Hosp.*, 221 USPQ 929, 933 (CAFC 1984).
>
> "There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge cannot come from the applicant's invention itself." *In re Oetiker*, 24 USPQ2d 1443, 1446 (CAFC 1992).
>
> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." *ACS Hosp. Sys. v. Montefiore Hosp.*, 221 USPQ 929, 933 (CAFC 1984) (footnote omitted).

12) Applicants have amended claim 1 to recite: "A therapeutic method for increasing cardiac output in a subject, the method comprising: creating a fistula between a systemic artery and a systemic vein of said subject, said fistula adapted to allow blood flow rate therethrough of at least 5 ml/min, wherein said blood flow through the fistula bypasses the peripheral microcirculation, and wherein creation of said fistula results in an increase in the cardiac output in said subject".

Applicants have amended claim 13 to recite: "An apparatus for increasing cardiac output in a subject, the apparatus comprising: a long-term implantable arteriovenous shunt device shaped and adapted for placement between a systemic artery and a systemic vein in said subject".

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

With reference to claim 1, Applicants submit that Douglas does not disclose a method for "creating a fistula between a systemic artery and a systemic vein". Applicants further submit that Douglas does not disclose a method "wherein said blood flow bypasses the peripheral microcirculation".

With reference to claim 13, Applicants submit that Douglas does not disclose an "arteriovenous shunt device". Applicants further submit that Douglas does not disclose a device "shaped and adapted for placement between a systemic artery and a systemic vein".

Applicants therefore submit that the prior art and the claimed invention are different. Applicants also submit that both the suggestion and the expectation of success must be founded on the prior art. Applicants submit that the disclosure of Douglas does not teach or suggest the claimed invention. Douglas discloses a shunt that connects one cardiac artery to another cardiac artery. The present invention discloses a lumen (a fistula or a shunt) used to connect a systemic artery and a systemic vein. The apparatus and method of Douglas bears very little resemblance in method, structure or function to the present claimed invention, the methods and devices of Douglas could not be used to practice or perform the current claimed invention, and the disclosure of Douglas does not teach or suggest methods or devices that are the same as or similar to those claimed.

Applicants respectfully note that the device disclosed by Douglas is for use in human subjects having a diseased heart, particularly congenital heart defects such as cyanotic heart disease. Douglas states at column 3, lines 40-41 "FIG.2 illustrates an example of a heart defect for which the present invention is applicable". Douglas discloses a shunt that is placed between the aorta and the pulmonary artery, both arterial blood vessels.

Applicants submit that were the device disclosed by Douglas be placed in a normal human heart between the aorta and the pulmonary artery as described in the methods disclosed by Douglas, the result would be clinically unfavorable as the procedure would increase pulmonary artery pressure leading to pulmonary hypertension and severe risk of death.

Applicants submit that the aim of the Douglas device is to provide the pulmonary artery of a subject having a heart defect (such as an atrial septal defect and a ventricle septal defect) with blood at a higher pressure so as to enable more blood to be oxygenated when passing through the pulmonary vasculature. The Douglas device is not disclosed to be used in the same manner to increase cardiac output as disclosed in the instant application.

Applicants submit, therefore, there would be no reasonable expectation of success if one of skill was to attempt to use the device and method of Douglas to provide the presently claimed invention, since Douglas discloses a shunt that connects only cardiac and pulmonary arteries, whereas the present invention discloses a fistula or a shunt to connect a systemic artery and a systemic vein. The apparatus and method of Douglas bears very little resemblance in method, structure or function to the present claimed invention; the apparatus and method of Douglas would in no way be applied to solve the current problem, could not be adapted to what is being done to solve the current problem, and could not be adapted to the way it is being done to solve the current problem.

Furthermore, Applicants submit that Douglas does not disclose the use of the Douglas device positioned between a systemic artery and a systemic vein resulting in increased cardiac output and decreased systemic vascular resistance as disclosed and claimed in Applicants' application; nor does Douglas teach or suggest that the Douglas device can be used in a normal heart or circulatory system to provide such clinical effects.

Applicants also submit that were the Douglas device to be placed between a systemic vein and the pulmonary artery, the result could be clinically unfavorable as the procedure would divert blood from the pulmonary artery to the systemic vein, increase venous

blood pressure in the vena cava, and increase blood flow into the right atrium of the heart, leading to possible congestion, cardiopathy, and risk of death.

Applicants submit, therefore, there would be no reasonable expectation of success to use the Douglas device between a vein and a pulmonary artery, since the vascular pressures would be different and the flow rate would be different to those disclosed by Douglas.

With reference to the Examiner's recitation that "Douglas discloses a method of reducing a patient's vascular resistance by using a resistor 110 to control fluidic flow through a shunt 100 implanted between the pulmonary artery and another systemic blood vessel which may be a vein" (see instant Office action at page 5, last four lines referring to Douglas at Figure 2 and column 1, lines 65-67 and column 2, lines 1-20, inspection of Douglas' Figure 2 shows that the Douglas device is positioned between the aorta and the pulmonary artery (both arteries). In addition, the recitation at Douglas column 1, lines 65-67 and column 2, lines 1-20 is directed to "precise control of blood flow through the shunt....is desirable to ameliorate the side-effects of increased ***pulmonary*** vascular resistance and volume overload of the ventricle" (emphasis added) and which clearly refers to side effects caused by a combination of the heart defect, the pulsatory nature of the heart contractions, and the variable blood flow through the Douglas device, and is not directed to disclosing that the Douglas device can be used between the pulmonary artery and a vein as stated by the Examiner (see instant Office action at page 5, last four lines).

Applicants submit that Douglas does not disclose using the Douglas device placed between an artery and a vein to increase cardiac output and to decrease ***systemic*** vascular resistance as disclosed and claimed in Applicants' application.

With regard to claim 15, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 13 indicate a holding of obviousness of dependent claim 15. Applicants therefore submit that Douglas does not read upon claim 15.

With regard to claims 3, 5, and 7, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 1 indicate a holding of obviousness of dependent claims 3, 5, and 7. Applicants therefore submit that Douglas does not read upon claims 3, 5, and 7.

With regard to claims 4, 6, and 8, Applicants again respectfully draw the Examiner's attention to the Examples section of the specification at page 19, paragraph 0056, at page 20, paragraphs 0057-0058, and also to the drawings disclosed in Figures 10, 11, and 12. Applicants therein clearly show experimental data that illustrates that the method of implanting an aorto-caval fistula in rats was associated with increased aortic blood flow (AF), with increased partial pressure of oxygen in arterial blood (PaO_2) in rats (Figure 10), and attenuates the development of pulmonary arterial hypertension (Figure 11). Applicants further submit that it is well known in the art that an increased partial pressure of oxygen in arterial blood (PaO_2) is associated with increased hemoglobin O_2 saturation in arterial or venous blood. In addition, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 1 indicate a holding of obviousness of dependent claims 4, 6, and 8. Applicants therefore submit that Douglas does not read upon claims 4, 6, and 8.

With regard to claims 10 and 19, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 13 indicate a holding of obviousness of dependent claims 10 and 19. Applicants therefore submit that Douglas does not read upon claims 10 and 19.

With regard to claim 11, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 1 indicate a holding of obviousness of dependent claim 11. Applicants therefore submit that Douglas does not read upon claim 11.

Applicants have amended claim 14 to recite: "The apparatus as set forth in claim 13, wherein said artery and said vein are selected from the group consisting of iliac artery

and vein, femoral artery and vein, axillary artery and vein, and subclavian artery and vein".

Applicants therefore submit that Douglas does not read upon claim 14. With regard to claim 14 and its recitation of the site of implantation of the claimed device, the Examiner stated that Douglas discloses that the shunt may be implanted between an aorta and another systemic blood vessel (see Douglas column 2, lines 11-15). Applicants respectfully submit that Douglas therein recites a shunt "used to provide a fluid path from the aorta (***or*** other systemic blood vessel) to the right, left, or main pulmonary artery" (emphasis added). Applicants therefore respectfully submit that Douglas does not disclose "that the shunt may be implanted between an aorta and another systemic blood vessel" as asserted by the Examiner.

In addition, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 13 indicate a holding of obviousness of dependent claim 14.

With regard to claim 20, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 13 indicate a holding of obviousness of dependent claim 20. Applicants therefore submit that Douglas does not read upon claim 20.

With regard to claim 21, Applicants' arguments and rebuttals regarding the Examiner's rejection of independent claim 13 indicate a holding of obviousness of dependent claim 21. Applicants therefore submit that Douglas does not read upon claim 21.

Applicants submit that the prior art and the claims at issue are different and therefore that claims 1, 3-11, 13-15, and 18-21 are not unpatentable over US 5,662,711 to Douglas.

Applicants therefore respectfully request that the Examiner withdraw the rejections of claims 1, 3-11, 13-15, and 18-21 under 35 USC § 103(a).

13) The Examiner has rejected claims 2 and 12 under 35 USC § 103(a) as being unpatentable over US 5,662,711 to Douglas in view of US 5,895,404 to Ruiz.

The Examiner stated that Douglas discloses a device substantially as claimed by Applicants with the exception of using a specific implantation procedure and implanting the shunt between the aorta and the inferior vena cava. The Examiner further stated that Ruiz discloses a method of treating a patient in need of cardiac therapy by percutaneously forming a passage between the aorta and the superior vena cava to treat complex single ventricle anatomy. The Examiner then stated that, absent a disclosure by Applicant that connection to the inferior vena cava produces an unexpected or beneficial result over connection to the superior vena cava, it was the position of the Examiner that connection (of the aorta) to the vena cava, in either the superior location or inferior location would be sufficient to provide therapeutic benefits as disclosed by Ruiz.

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." *ACS Hosp. Sys. v. Montefiore Hosp.*, 221 USPQ 929, 933 (CAFC 1984) (footnote omitted).

14) Applicants have amended claim 2 to recite: "The method as set forth in claim 1, wherein said artery and said vein are selected from the group consisting of iliac artery and vein, femoral artery and vein, axillary artery and vein, and subclavian artery and vein".

Applicants have amended claim 12 to recite: "The method as set forth in claim 1, wherein said fistula is created via an open surgical procedure, a minimally invasive surgical procedure, or an intravascular procedure".

Applicants therefore submit that the prior art and the claimed invention are different. As discussed above, Douglas does not teach nor suggest the apparatus or methods of the

instant claimed invention and the teachings of Douglas would have no expectation of success to solve the current problem. Therefore the combination of Douglas and Ruiz cannot make obvious the invention.

Douglas does not recite or show each element of the invention and therefore a combination of the teachings of Douglas and Ruiz would have no reasonable expectation of success. Applicants therefore submit that the prior art and the claims at issue are different and therefore that claims 2 and 12 are not unpatentable over US 5,662,711 to Douglas in view of US 5,895,404 to Ruiz.

Applicants therefore respectfully request that the Examiner withdraw the rejections of claims 2 and 12 under 35 USC § 103(a).

15) The Examiner has rejected claims 16 and 17 under 35 USC § 103(a) as being unpatentable over US 5,662,711 to Douglas in view of US 6,569,128 to Christensen et al..

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." *ACS Hosp. Sys. v. Montefiore Hosp.*, 221 USPQ 929, 933 (CAFC 1984) (footnote omitted).

16) Applicants submit that the prior art and the claimed invention are different. As discussed above, Douglas does not teach nor suggest the apparatus or methods of the instant claimed invention and the teachings of Douglas would have no expectation of success to solve the current problem. Therefore the combination of Douglas and Christensen et al. cannot make obvious the invention.

Douglas does not recite or show each element of the invention and therefore a combination of the teachings of Douglas and Christensen et al. would have no reasonable

expectation of success. Applicants submit that the prior art and the claims at issue are different and therefore that claims 16 and 17 are not unpatentable over US 5,662,711 to Douglas in view of US 6,569,128 to Christensen et al..

Applicants therefore respectfully request that the Examiner withdraw the rejections of claims 16 and 17 under 35 USC § 103(a).

17) The Examiner has rejected claim 22 under 35 USC § 103(a) as being unpatentable over US 5,662,711 to Douglas in view of US 5,867,718 to Fischer et al..

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." *ACS Hosp. Sys. v. Montefiore Hosp.*, 221 USPQ 929, 933 (CAFC 1984) (footnote omitted).

18) Applicants therefore submit that the prior art and the claimed invention are different. As discussed above, Douglas does not teach nor suggest the apparatus or methods of the instant claimed invention and the teachings of Douglas would have no expectation of success to solve the current problem. Therefore the combination of Douglas and Fischer et al. cannot make obvious the invention.

Douglas does not recite or show each element of the invention and therefore a combination of the teachings of Douglas and Fischer et al. would have no reasonable expectation of success. Applicants submit that the prior art and the claims at issue are different and therefore that claim 22 is not unpatentable over US 5,662,711 to Douglas in view of US 5,867,718 to Fischer et al..

Applicants therefore respectfully request that the Examiner withdraw the rejection of claim 22 under 35 USC § 103(a).

CONCLUSION

With these arguments, Applicants believe that the application is in condition for allowance. If the US Patent Office believes that communication would further the prosecution of this application, then the appropriate US Patent Office personnel are invited to contact the Applicants' below-signed representative at their earliest convenience.

If the Commissioner finds any additional charges or fees must be paid in connection with this communication, they may be paid out of Bell & Associates Deposit Account No. 50-3194.

Dated and signed:

27th March 2007

Matthew Kaser, D.Phil.
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